

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Li, Guoqiao et al.

Application No.: 10/587,277

Confirmation No.: 4870

Filed: July 25, 2006

Art Unit: 1616

For: COMPOUND ARTEMISININ

Examiner: Arnold, Ernst V

**RULE 1.132 DECLARATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

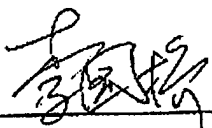
Dear Sir:

1. We, Guoqiao Li and Jianping Song, are citizens of China and reside at Guangzhou, China, hereby declare and say as follows:
2. We are the named inventors of this application, U.S. Application No.: 10/587,277 (" '277 application").
3. We have read and reviewed the '277 application.
4. We conducted clinical trials to treat the patients with malaria and compared the formulation of the '277 application with the formulation of dihydroartemisinin and piperaquine phosphate for various side effects. The results are as follows.

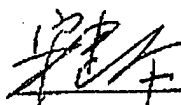
Side effects	The present combination in the '277 application (artemisinin+piperaquine+primaquine)	The compared formulation (dihydroartemisinin+piperaquine phosphate)
Reduced appetite	1.4%	2.8%
Nausea	3.2%	6.6%
Vomiting	2.1%	6.6%
Diarrhea	1.0%	2.8%
Abdominal pain	1.0%	1.9%
Headache	0.8%	2.8%
Dizziness	1.4%	4.7%
Insomnia	0.6%	2.8%
Tiredness	0.6%	0.9%

The data in the above table show that the incidence of side effects caused by the present combination is lower than that caused by the formulation of dihydroartemisinin + piperazine phosphate, and thus the present combination is safer than the formulation of dihydroartemisinin + piperazine phosphate.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

  
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Guoqiao Li

March 13, 2009  
Date

  
\_\_\_\_\_  
Jianping Song

March 13, 2009  
Date